

REMARKS

Page 35 has been amended to delete a reference to the attorney docket number in the heading to the page, and to add the phrase "what is claimed is" above claim 1.

Claims 1, 11 and 19 have been amended.

35 U.S.C. §102

MPEP 2131 quotes Verdegaal Brothers v. Union Oil of California, 814 F.2d 628, 631 (Fed. Cir. 1987) for the legal standard of anticipation: "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." (emphasis added).

Claims 1-10

Claim 1 has been amended to claim a "system for performing anastomosis between a graft vessel and a target vessel, each having a lumen therethrough, where an opening is present in wall of the target vessel; the system comprising: an inner element connectable to the graft vessel, said inner element including a unitary body having a closed perimeter and an opening therethrough within said perimeter; wherein at least a portion of said unitary body is deformable from a first configuration to a second configuration and deformable back to said first configuration from said second configuration, wherein said second configuration allows at least a portion of said unitary body to enter the opening in the target vessel."

In contrast, U.S. Patent Application Publication No. 2003/0153933 of Bolduc et. al. ("Bolduc") neither explicitly nor implicitly describes each and every element of amended claim 1. First, the Office Action identifies a hook 80 of Bolduc as corresponding to the claimed inner element. A plurality of hooks are utilized, and each one is "U-shaped." (e.g., Bolduc, paragraph 0065; Figures 18-19, 24-30B) Thus, each inner element of Bolduc has an

open perimeter, instead of the closed perimeter claimed in amended claim 1. Second, amended claim 1 claims an "inner element including a unitary body." In contrast, Bolduc utilizes "a plurality of tissue securing members" to connect the graft vessel to the target vessel, where "the preferred tissue securing members comprise hooks 80." (e.g., Bolduc, paragraph 0065; Figures 18, 24) (emphasis added). Thus, Bolduc discloses a plurality of inner elements. Thus, Bolduc neither discloses nor suggests a unitary inner element as claimed in amended claim 1. Indeed, Bolduc teaches away from a unitary inner element by disclosing only a plurality of separate, discrete hooks 80.

Thus, Bolduc neither expressly nor inherently describes each and every element claimed in claim 1, and Applicants believe claim 1 is in condition for allowance. Claims 2-10 depend directly or indirectly from claim 1, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

In addition, the inherency rejection with regard to claims 1-10 is unsupported. "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." MPEP 2112 (citing *Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990)) (emphasis in original). The Office Action merely states that "Bolduc et. al....is found to be inherently capable of performing the functions." (Office Action, page 3). No basis in fact or technical reasoning was set forth. Thus, Applicants respectfully request that the rejection of claims 1-10 on the grounds of inherency be withdrawn.

Claims 11-18

Claim 11 has been amended to claim a "system for performing anastomosis between a graft vessel and a target vessel, each having a lumen therethrough, where an opening is

present in the wall of the target vessel; the system comprising: a single elastically deformable inner element connectable to the graft vessel, said inner element deflectable from a first configuration to a second configuration and expandable from said second configuration to said first configuration, wherein said second configuration allows at least a portion of said inner element to enter the lumen of the target vessel through the opening; and an outer element connectable to said inner element to compress a portion of the graft vessel and a portion of the target vessel therebetween."

In contrast, Bolduc neither explicitly nor implicitly describes each and every element of amended claim 11. The Office Action identifies a hook 80 of Bolduc as corresponding to the claimed inner element. Bolduc discloses "a plurality of tissue securing members," where "the preferred tissue securing members comprise hooks 80." (e.g., Bolduc, paragraph 0065; Figures 18, 24) (emphasis added). Thus, Bolduc discloses a plurality of inner elements. In contrast, amended claim 11 claims "a single elastically deformable inner element." Indeed, Bolduc teaches away from a single inner element by disclosing only a plurality of separate, discrete inner elements 80.

Thus, Bolduc neither expressly nor inherently describes each and every element claimed in claim 11, and Applicants believe claim 11 is in condition for allowance. Claims 12-18 depend directly or indirectly from claim 11, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

In addition, the inherency rejection with regard to claims 1-10 is unsupported, as discussed above with respect to claim 1. Thus, Applicants respectfully request that the rejection of claims 11-18 on the grounds of inherency be withdrawn.

Claims 19-25

Claim 19 has been amended to claim a "method for performing anastomosis between a graft vessel and a target vessel, each having a lumen therethrough, where an opening is present in the target vessel, comprising: providing an outer element and an inner element, said inner element including a unitary body having a closed perimeter and an opening therethrough within said perimeter; deforming at least a portion of said unitary body from an initial configuration to a compressed configuration; inserting at least part of said unitary body into the opening; expanding at least a portion of said unitary body from said compressed configuration to said initial configuration; and compressing a portion of the target vessel and a portion of the graft vessel together between at least a portion of said inner element and at least a portion of said outer element."

The same discussion applies here as with regard to claims 1-10. Thus, Bolduc neither discloses nor suggests each and every element claimed in amended claim 19, and Applicants believe claim 19 is in condition for allowance. Claims 20-25 depend directly or indirectly from claim 19, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

REQUEST FOR ALLOWANCE

Allowance of the pending claims is respectfully solicited. Please contact the undersigned if there are any questions.

Respectfully submitted,



Brian A. Schar
Attorney for Applicants
Reg. No. 45,076
Tel. No. (650) 331-7162
Chief Patent Counsel
Cardica, Inc.